

which are distinctly different from the properties of dry powders which are obtained when another protective colloid and/or another sugar are employed.

More particularly, applicants have prepared astaxanthin dry powders in the manner described for Example 1, page 11, indicated lines 17 to 41, of the application:

- A first sample (A) representing applicants' invention was prepared using soybean protein instead of the partially degraded soybean protein employed in Example 1.
- A second sample (B) was prepared for comparison using soybean protein instead of the the partially degraded soybean protein employed in Example 1, and using glucose instead of the lactose employed in Example 1.
- A third sample (C) was prepared for comparison using casein instead of the partially degraded soybean protein employed in Example 1.
- A fourth sample (D) was prepared for comparison using gelatine instead of the partially degraded soybean protein employed in Example 1.

After determining the astaxanthin content of the dry powders (A) to (D), the samples were stored at 60°C for a period of 40 days. After the storage period the astaxanthin content of the dry powders (A) to (D) was measured again. The respective data are compiled in the following table:

Sample	Protective Colloid / Sugar	Carotenoid Content before Storage (%)	Carotenoid Content after Storage (%)	Carotenoid Loss upon Storage (%)
(A)	soybean protein / lactose	13.7	11.4	16.5
(B)	soybean protein / glucose	13.5	9.4	30.2
(C)	casein / lactose	13.1	8.8	32.5
(D)	gelatine / lactose	11.3	5.9	48.3

The data show that the nature of the protective colloid and of the sugar which are employed in combination with one another has a distinct and unexpected impact on the storage stability of the carotenoid dry powder. When the soybean protein / lactose combination in accordance with applicants' invention as illustrated by sample (A) was used, the carotenoid content of the dry powder was reduced upon storage by 16.5%. However, when the lactose was replaced by glucose as illustrated by sample (B), the carotenoid loss upon storage

amounted to 30.2% which is almost twice the loss suffered by sample (A). Similarly, when lactose was used as the sugar but the soybean protein was replaced by another protective colloid as illustrated by samples (C) and (D), the carotenoid loss upon storage increased to 32.5% and 48.3%, respectively.

As pointed out by applicants in their preliminary remarks the teachings of *Jensen et al.*, *Dobler et al.* and *Horn et al.* convey to a person of ordinary skill in the art that powders comprising a carotenoid have essentially the same properties as long as the protective colloid selected from the group of

- a₁) a hydrocolloid including "extrudates, such as gum arabic, tragacanth, gum karaya, gum ghatti; extracts from seaweed, such as agar, alginate, carrageenan and furcellaran; extracts from plants, such as pectin and arabinogalactan; extracts from marine and terrestrial animals, such as gelatines and other proteinaceous hydrocolloids, flours from seeds, such as guar, locus bean, soy bean; proteins from seeds, such as soya bean protein; flours from cereals, such as starches and microcrystalline cellulose; biosynthetic or fermentation derived hydrocolloids, such as cellulose derivatives, including methyl cellulose, and other derivatives, including modified starches and low methoxy pectin; synthetic hydrocolloids, such as polyvinylpyrrolidon, carboxyvinyl polymers, etc."¹); or
- a₂) "partially degraded soybean proteins which preferably have a degree of degradation ... of 0.1 to 5% ..." ²); or
- a₃) swellable colloids such as "gelatin, starch, dextrin, pectin, gum arabic, casein, caseinate ... polyvinyl alcohol, polyvinylpyrrolidone, methylcellulose, carboxymethylcellulose, hydroxypropylcellulose and alginates"³),

is used in combination with

- b₁) "dissolved carbohydrate, such as sorbitol and sucrose", as excipient⁴); or

1) Cf. the teaching of *Jensen et al.* on page 4, indicated line 35, to page 5, indicated line 9, of *WO 91/06292*.

2) Cf. the teaching of *Dobler et al.* on page 3, indicated lines 4 to 7, of *WO 96/01570*.

3) Cf. the teaching of *Horn et al.* in col. 3, indicated lines 27 to 32, of *US 4,582,743*.

4) Cf. the teaching of *Jensen et al.* on page 5, indicated lines 19 to 22, of *WO 91/06292*.

- b₂) "sugars or sugar alcohols, starch or starch derivatives, stabilizers ... as well as emulsifiers ..." as conventional auxiliaries⁵); or
- b₃) "sugars or sugar alcohols, eg. sucrose, glucose, lactose, invert sugar, sorbitol, mannitol or glycerol", to increase the mechanical stability of swellable colloids⁶).

A person of ordinary skill in the art could therefore not reasonably expect to find that the nature of the colloid and the nature of the sugar which are employed in the preparation of carotenoid powders are of significance with regard to the properties of the powders. The data contained in the application and the supplemental data addressed in the foregoing corroborate that applicants' combined use of soybean protein and lactose provides for distinctly improved properties could not reasonably be expected based on the teachings of *Jensen et al.*, *Dobler et al.* and *Horn et al.*

Section 103(a) refers to "the invention as a whole" and it is well settled that the invention as a whole which is referenced in Section 103(a) embraces not only the subject matter particularly recited in the claims, but also the properties and results of such subject matter which arise from the claimed combination⁷). The teachings of *Jensen et al.*, *Dobler et al.* and *Horn et al.* -taken alone or taken in combination or one taken in view of the other- clearly fail to suggest or imply that the properties of a carotenoid dry powder can be altered or can be significantly improved when a specific group of protective colloids and a specific sugar are selected and combined. As such, the teachings of *Jensen et al.*, *Dobler et al.* and *Horn et al.* -taken alone or taken in combination or one taken in view of the other- clearly fail to render applicants' invention prima facie obvious within the meaning of Section 103(a).

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5) Cf. the teaching of *Dobler et al.* on page 4, indicated lines 6 to 11, of *WO 96/01570*.

6) Cf. the teaching of *Horn et al.* in col. 3, indicated lines 35 to 39, of *US 4,582,743*.

7) Cf. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); *In re Wright*, 848 F.2d 1216, 6 USPQ2d 1959 (Fed. Cir. 1988), overruled on other grounds in *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990) (*en banc*), cert. denied 500 U.S. 904 (1991).

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Respectfully submitted,

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A handwritten signature in cursive script, appearing to read "Dan Kim".

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